A Phase 1b/2a Study of the ROR1-Targeting Monoclonal Antibody, Cirmtuzumab, and the Bruton Tyrosine Kinase Inhibitor, Ibrutinib, in B-Cell Cancers

Grant Award Details

A Phase 1b/2a Study of the ROR1-Targeting Monoclonal Antibody, Cirmtuzumab, and the Bruton Tyrosine Kinase Inhibitor, Ibrutinib, in B-Cell Cancers

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-10192

Project Objective: To complete a Phase 1b/2a study that will assess the safety, pharmacology, and efficacy of cirmtuzumab when given alone or in combination with ibrutinib to patients with CLL/SLL and MCL.

Investigator:

Name:	Thomas Kipps
Institution:	University of California, San Diego
Type:	PI

Disease Focus: Blood Cancer, Cancer, Leukemia

Award Value: $18,292,674

Status: Active

Grant Application Details

Application Title: A Phase 1b/2a Study of the ROR1-Targeting Monoclonal Antibody, Cirmtuzumab, and the Bruton Tyrosine Kinase Inhibitor, Ibrutinib, in B-Cell Cancers

Public Abstract:

Therapeutic Candidate or Device

Cirmtuzumab (UC-961) is a therapeutic monoclonal antibody that inhibits ROR1, a tumor-specific protein on the surface of many cancer stem cells

Indication

Cirmtuzumab will be used with the approved drug, ibrutinib, for patients with chronic lymphocytic leukemia or mantle cell lymphoma

Therapeutic Mechanism

ROR1 is a cell surface protein which is present on tumors but not normal adult tissues, making it an attractive target for anticancer therapy. ROR1 is expressed on the malignant cells in >90% of patients with chronic lymphocytic leukemia or mantle cell lymphoma, and is commonly seen on multiple solid tumors, where it is a marker of cancer stem cells. Binding of cirmtuzumab inhibits ROR1 cellular actions, thereby disrupting processes important for cancer growth

Unmet Medical Need

Ibrutinib, a current therapy for chronic lymphocytic leukemia and mantle cell lymphoma, causes complete disease remission in <20% of patients. Combining cirmtuzumab with ibrutinib is proposed to significantly increase the proportion of patients with complete remission and long-term cancer control.

Project Objective

Cirmtuzumab manufactured, Ph 1b/2a trial completed

Major Proposed Activities

- Manufacture cirmtuzumab monoclonal antibody for use in the Phase 1b/2a clinical trial
- Perform a Phase 1b/2a study to demonstrate the safety, pharmacology, and efficacy of cirmtuzumab when given together with ibrutinib.

Statement of Benefit to California:

This research can directly benefit many of the 103,000 Californians living with leukemia and lymphoma, particularly those with chronic lymphocytic leukemia or mantle cell lymphoma. The planned clinical trial will move cirmtuzumab towards Food and Drug Administration approval, making it available throughout California and the United States, thereby creating medical and economic value for California patients and citizens and showcasing CIRM as a positive force for health science progress.

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